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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/600,812 | 06/20/2003 | Frank Bonadio | 08203.0030-01 | 7588 |
| 22852 | 7590 | 11/05/2007 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | EXAMINER BIANCO, PATRICIA | |
| | | | ART UNIT 3772 | PAPER NUMBER |
| | | | MAIL DATE 11/05/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 10/600,812 | BONADIO ET AL. | |
| Examiner | Art Unit | | |
| Patricia M. Bianco | 3772 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 January 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 25-55 and 72-104 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 25-55 and 72-104 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/22/05.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 1/05/06 have been fully considered but they are not persuasive. Further, Applicant's arguments with respect to the priority claim have been considered but are not persuasive. Also, there are newly presented rejections to 35 U.S.C. 102(g) presented below.

Applicant argues that the patented claims of Leahy are not so broad as to "cover" a surgical device and method of providing sealed access through an incision "without the use of adhesive" as set forth in the Office Action mailed July 5, 2005. Applicant also argues that the apparatus claimed is a "single patient coupling assembly" as required by the claims. Applicant further argues that the distal ring and diaphragm together form the only coupling with the patient's body, as shown in figure 9 of the present application, and does not require the use of, for example, an adhesive. The examiner respectfully disagrees. It is the position of the examiner that the device of Leahy does in fact provide a single coupling with the patient's body through the incision of only the ring and diaphragm as shown below in figure 19 (see body of 102 (e) rejection below). The adhesive layer in the Leahy device is not part of the coupling device nor is it needed for attaching the coupling to the body; it is taught to attach the surgical device to a drape (shown as D in figure 19). Further, applicant's claim construction includes the transition phrase "comprising" which is an open-ended limitation. Thus, the inclusion of the adhesive attaching a drape to a patient is not precluded from the claim construction of the pending claims.

Applicant further argues that the pending claims are not estopped under 37 CFR 41.127(a)(1). The examiner respectfully disagrees. Applicant's filing of a continuing application with claims 25-40, 101 and 102 to the method of providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference. Applicant's filing of a continuing application with claims 25-40, 101 and 102 to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count. The claims must be rejected as estopped on the merits by the applicant's loss in the interference, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims. As noted above, the position of the examiner is that the device of Leahy is a "single"coupling assembly and as such the claims of the instant application would have been supported by the disclosure of Leahy.

Applicant further argues that they are entitled to the priority date of at least Irish Patent Application No. 930649. The examiner respectfully disagrees. The Board of Patent Appeals and Interferences held that as a matter of law, the Party Bonadio, et al. is not entitled to the benefit of priority in their U.S. application of the earlier filed Irish applications an the PCT applications, because the current named individuals, Bonadio and Reid, are not the same inventive entities as the individuals named in Party Bonadio et al.'s Irish and PCT priority applications. According to §201.15 of the MPEP:

"The foreign application may have been filed by and in the name of the assignee or legal representative or agent of the inventor, as applicant. In such cases, if the certified copy

of the foreign application corresponds with the one identified in the oath or declaration as required by 37 CFR 1.63 and no discrepancies appear, it may be assumed that the inventors are entitled

to the claim for priority. If there is a disagreement as to inventors on the certified copy, the priority date should be refused until the inconsistency of disagreement is resolved." [Emphasis added]

See Motion under 37 C.F.R 1.633(g) in Interference No. 104,195.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

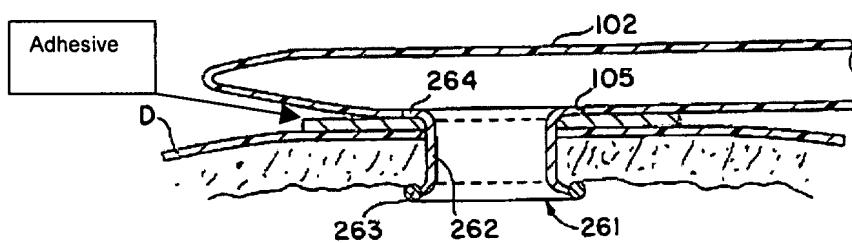
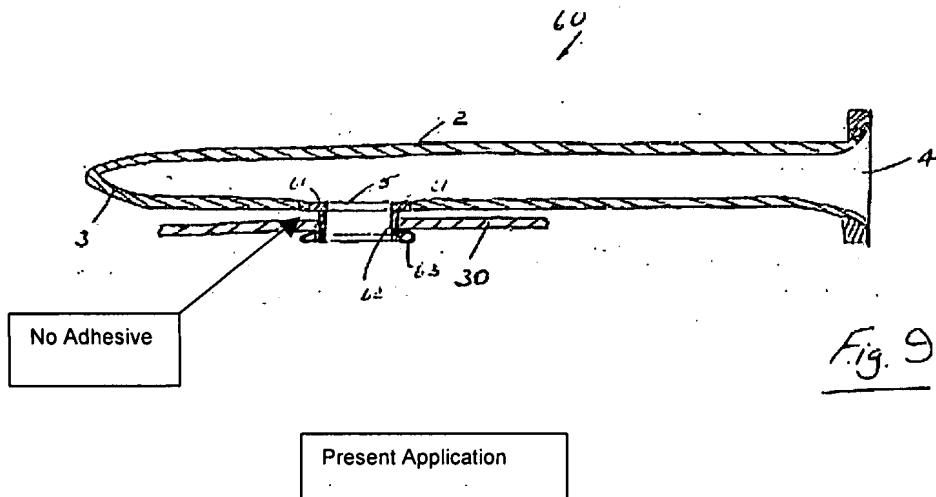
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 25-55 and 72-104 are rejected under 35 U.S.C. 102(e) as being anticipated by Leahy (U.S. Patent No. 5,640,977). Leahy anticipates the claimed invention because of admissions made by Applicant during an interference proceeding, during an Examiner's Interview on March 23, 2005 and given the fact that Leahy was declared the winning party of the interference.

During the interview on March 23, Applicant and his attorney made the following admissions:

- 1) Claims 25-85 of the present application are directed only at the embodiment shown in Figure 9.
- 2) In comparison to the Leahy patent, the only difference between Figure 9 of the present invention and Figure 19 of the Leahy patent is that the Leahy patent includes an adhesive whereas Figure 9 of the present application does not illustrate an adhesive (see below).



U.S. Patent No. 5,640977

The Office takes the position that the scope of the patented claims of Leahy are so broad they also cover a surgical device and method of providing sealed access through an incision without the use of an adhesive, as is evident by the claims. For instance, independent claims 1, 20, and 28 of the Leahy patent do not recite the limitation of an adhesive. The claims of the Leahy patent only recite the adhesive in dependent claims such as claims 6, 7, and 24. The patented claims, which do not

mention the adhesive or depend upon such a claim, do not require the adhesive. Therefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate claims 25-55 and 72-104 of the present application. It is the Office's position that the claims of the present invention is directed to the same invention patentable invention lost during the interference. Since Leahy won the interference and it was ordered that the present invention is not entitled to a patent which covers the claims won by Leahy during the interference. The present invention is not entitled to a patent containing the claims corresponding to the count or counts of the interference as ordered by the Board's judgment.

Furthermore, during the interference, applicant admitted in Appendix A of the Amendment filed on January 5, 1997 that claim 28 of the Leahy patent reads upon Fig. 9. (A courtesy copy has been attached.) In order to invoke the interference, on page 6 of Appendix A, Applicant compared patented claim 28 to Fig. 9 of the present application. Applicant's comparison and analysis of patented claim 28 does not indicate that the adhesive or flange is required when interpreting the scope of this claim. Thus, Applicant acknowledges that the Leahy's device can be used without an adhesive and covers the embodiment of Figure 9 of the present application.

Furthermore, claims 25-40, 101 and 102 directed to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims. It is obvious

to one having skill in the art that in order to provide a sealed access through an incision one must perform the claimed step of "making an incision in a patient" as well as the step of "providing a surgical device...." followed by the step of "inserting an object through an entry seal assembly coupled to the surgical device" as recited by the claims. The specific structure of the surgical device, as recited in the claims, is taught by Leahy. As a result, the method as claimed would have been obvious when one of ordinary skill used the device of Leahy.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 25-55 and 72-104 are rejected under 35 U.S.C. 102(g) over the sole lost count of Patent Interference No. 104,195.

Claims 25-55 and 72-104 correspond to the subject matter of the sole count of Patent Interference No. 104,195, as to which a judgment adverse to the applicant has been rendered. A losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992); *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985). See also MPEP §2308.03.

This rejection incorporates the principles of res judica and collateral estoppel as independent claims 25, 41, 72 and 86 are rejected as not patentably distinct from the subject matter of the lost count.

Applicant lost on priority for a count drawn to subject matter to a surgical device for providing sealed access through an incision in a patient. The Board's judgment automatically disposed of all of the applicant's claims corresponding the count. Applicant's filing of a continuing application with claims 41-55, 72-100, 103 and 104 to the subject matter to a surgical device for providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference.

Further, applicant's claim(s) was held unpatentable during the interference. Applicant could have moved, but did not move, to amend the claim(s). Now, applicant has filed a continuing application with amended claims. The subject matter of the amended claims would have been anticipated or obvious in view of the sole count of the interferences and the claims must be rejected as procedurally estopped. Whether the amendment is sufficient to overcome the ground for unpatentability or not, the time to have amended the claim(s) was during the interference.

Applicant lost on priority for a count drawn to subject matter to a surgical device for providing sealed access through an incision in a patient. The Board's judgment automatically disposed of all of the applicant's claims corresponding the count. Applicant's filing of a continuing application with claims 25-40, 101 and 102 to the method of providing sealed access through an incision in a patient must be rejected as

estopped on the merits by the applicant's loss in the interference. Applicant's filing of a continuing application with claims 25-40, 101 and 102 to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count. The claims must be rejected as estopped on the merits by the applicant's loss in the interference, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims.

Furthermore, no second interference should occur between the same parties on patentably indistinct subject matter. If the Board of Patent Appeals and Interferences held that there is no interference-in-fact between the parties for the subject matter of the count, that holding may not be reopened in further examination. If a party that lost the earlier interference is again claiming the same invention as the count, the interfering claims should be rejected as estopped. See also MPEP §2308.03(c).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-271-7143.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia M Bianco
SPE
Art Unit 3772


PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700